



WARNING LETTER

March 30, 2009

Richard J. Meelia
Chairman, President and Chief Executive Officer
Mallinckrodt Inc. Pharmaceuticals Group
675 McDonnell Blvd.
St. Louis, MO 63134

Product:
Morphine Sulfate Concentrate Oral Solution 20mg/ml

Dear Mr. Meelia:

This letter is written in reference to your firm's marketing of an unapproved new drug in violation of the Federal Food, Drug, and Cosmetic Act (the Act). Based on the information your firm submitted to FDA's Drug Registration and Listing System, you manufacture and distribute the following prescription drug:

- Morphine Sulfate Concentrate Oral Solution 20mg/ml

As labeled, the above product is a drug within the meaning of section 201(g)(1)(B) and (C) of the Act [21 U.S.C. §§ 321(g)(1)(B) and (C)] because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and because it is intended to affect the structure or function of the body. Further, this drug product as manufactured and distributed by your firm is a "new drug" within the meaning of section 201(p) of the Act [21 U.S.C. § 321(p)] because it is not generally recognized as safe and effective for its labeled uses. Under sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an application approved by FDA under either section 505(b) or (j) of the Act [21 U.S.C. § 355(b) or (j)] is in effect for the product. Based upon our information, there is no FDA-approved application on file for the above product. The marketing of this product without an approved application constitutes a violation of these provisions of the Act.

Additionally, because the above product is intended for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written for it so that a layman can use this product safely for its intended uses. Consequently, its labeling fails to bear adequate directions for its intended uses, causing it to be misbranded under section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)]. Because your product lacks a required approved application, it is not exempt under 21 C.F.R. § 201.115 from the requirements of section 502(f)(1) of the Act. The introduction or delivery for introduction into interstate commerce of this product therefore violates sections 301(a) and (d) of the Act [21 U.S.C. §§ 331(a) and (d)].

As described in the guidance entitled "Marketed Unapproved Drugs - Compliance Policy Guide"¹ the Agency may exercise its enforcement discretion and identify a period of time during which the Agency does not intend to initiate an enforcement action against a currently marketed unapproved drug. FDA does not intend to initiate enforcement actions related to your unapproved drug product Morphine Sulfate Oral Solution 20mg/ml that is being manufactured as of the date of this letter, unless the manufacturing of this product continues more than 60 days after the date of this letter. Furthermore, FDA does not intend to initiate enforcement actions related to the shipment in interstate commerce of this product unless it is still being shipped more than 90 days after the date of this letter.

You should be aware that FDA's enforcement discretion will not apply to the following circumstances: (1) if FDA determines that your firm is violating other provisions of the Act; (2) if it appears that your firm, in response to this letter, increases its manufacture or distribution of your unapproved product, Morphine Sulfate Concentrate Oral Solution 20mg/ml, above your usual volume during these periods; or (3) if FDA learns of new information regarding any serious health risk or hazard associated with morphine sulfate drug products.

The violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your product. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of Federal law and FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other Federal agencies may take this Warning Letter into account when considering the award of contracts.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing regarding whether you plan to cease the violative activities described in this

¹ Marketed Unapproved Drugs—Compliance Policy Guide. Available at <http://www.fda.gov/cder/guidance/6911f1.pdf>

letter. If you no longer manufacture or market the product referenced in this letter, your response should so indicate, including the reasons that, and the date on which, you ceased production. Additionally, if another firm manufactures the product identified above, your reply should include the name and address of the manufacturer. If the firm from which you receive this product is not the manufacturer, please include the name of your supplier in addition to the manufacturer.

Your response to this letter should be directed to the attention of Ms. Sakineh Walther, Consumer Safety Officer, at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, WO51 RM 5242, 10903 New Hampshire Avenue, Silver Spring, MD 20993.

Sincerely,

/s/

Deborah M. Autor, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration